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REGULATORY STATUS STATEMENT

Berberine HCl 97%

This statement summarises the regulatory position of Berberine HCl 97% in the principal markets as of the document date and supports the customer's own compliance assessment of its finished product. It is provided for general guidance and does not constitute legal advice.

1. Regulatory status in major markets

Market / jurisdiction	Regulatory framework	Status / classification	Basis / documentation	Remarks
United States (FDA)	DSHEA 1994; 21 CFR Part 101; Part 111	Marketed as a dietary ingredient under DSHEA, with finished products made under 21 CFR Part 111. No food-additive listing and not an approved colour additive. No GRAS notice or NDI notification filed by us.	DSHEA 1994; 21 CFR 101; 111	Finished-product use, dosage and claims: customer to confirm.
European Union (EFSA / European Commission)	Reg. (EU) 2015/2283; Reg. (EC) 1924/2006	Not an authorised food additive. A purified berberine salt has no pre-1997 consumption history in the Union and falls within the novel-food definition; no Union authorisation is held, and several member states restrict it in supplements. No health claim is authorised.	2015/2283; 1924/2006	Novel-food status in the destination member state: customer to determine.
China (NMPA / SAMR)	Drug registration (OTC chemical drug); GB 7718	Registered as an over-the-counter chemical drug, with the indication limited to intestinal infections. Not a permitted ordinary food ingredient and not a new food raw material. Offered as an export raw material.	Drug standard; GB 7718	Domestic use and finished-product registration: customer to determine.
Codex Alimentarius (FAO / WHO)	Codex GSFA; Codex labelling standards	No Codex commodity standard exists and JECFA has issued no specification; not listed in the Codex General Standard for Food Additives.	Codex GSFA	Customer to confirm.
Canada (Health Canada / NNHPD)	Natural Health Products Regulations	Recognised as a natural-health-product medicinal ingredient; the finished product needs a licence and NPN. None is held by us.	NHP Regulations	Permitted monograph conditions and claims: customer to determine.
Australia / New Zealand (TGA / FSANZ)	Therapeutic Goods Act; Food Standards Code	Supplied to the complementary-medicine sector as a listed medicine. Food use would require a novel-food assessment. No ARTG listing is held by us.	Therapeutic Goods Act; FSANZ	Customer to determine the listing or food route.
Other markets	National food and medicine law	Classification depends on the intended use and the jurisdiction.	Applicable national law	Customer to determine.

2. Other

- The article is a single purified alkaloid salt, isolated from *Berberis vulgaris* rhizome and crystallised to not less than 97.0% berberine hydrochloride on the dried basis; no excipient, carrier or additive is present.
- Berberine is pharmacologically active. It inhibits CYP3A4 and P-glycoprotein and may raise exposure to co-administered medicines; finished-product labels should carry the interaction warnings required in the destination market. Use in pregnancy, lactation and in G6PD deficiency is advised against.
- Not listed on the WADA Prohibited List and not a controlled substance in major sports jurisdictions.

Classification applies to the ingredient as supplied; finished-product and supplement status remain the customer's responsibility.

Prepared by: Mia Yu Approved by: Charlie Wang Date: Nov. 18, 2026